



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

*[Handwritten signature]*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,647	07/17/2001	Ramachandran Murali	UPN-3963	3796

7278      7590      06/17/2005  
DARBY & DARBY P.C.  
P. O. BOX 5257  
NEW YORK, NY 10150-5257

EXAMINER

LY, CHEYNE D

ART UNIT      PAPER NUMBER

1631

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/720,647

Applicant(s)

MURALI ET AL.

Examiner

Cheyne D. Ly

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10/15/04; 12/13/04; 3/09/05; 8/16/04
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 9-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-8 and 25-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/29/04; 5/20/05.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

Art Unit: 1631

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 16, 2004 has been entered.

2. Applicants' arguments have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

3. Applicant's summary of the interview conducted on September 22, 2004, has been accepted.

4. Claims 1, 6-8, and 25-30 are examined on the merits.

### **RESPONSE TO ARGUMENTS**

5. In the REMARKS section, filed March 09, 2005, Applicant states that Applicant "disagree that a new claim can be construed as containing a proposed amendment. Further, Applicant points to the MPEP 714.03(c) to argue that the amendments, filed October 15, 2004, and December 13, 2004, were "bona fide attempts to advance the application, and the deficiencies were of the minor nature indicated by the MPEP that could have been acted on by the Examiner..." Applicant's pointed section of the MPEP has been noted.

Art Unit: 1631

6. As to the issues identified in the Office communications, mailed December 07, 2004 and March 03, 2005, these issues are not issues of “the minor nature” as asserted by Applicant. For example, the Communication, mailed December 07, 2004, is directed to the issue of the claims not having the permissible identifiers as required by the MPEP. The issues needed to be resolved as required by the MPEP 714 [R-2] in order to advance prosecution.

#### **CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claim 29, line 4, recites the limitation of “a predetermined biological” which causes said claim to be vague and indefinite because the adjective “biological” does not modify a noun. Clarification of the metes and bounds is required.

#### **Claim Rejections - 35 USC § 112**

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that

Art Unit: 1631

the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER REJECTION.

12. Claim 25 recites “identifying thermal B-factors, using calorimetric values from thermodynamic, or using computer simulation algorithms” has not been found in the instant specification. The specification on page 10 describes thermal B-factors are identified from NMR signals, or microcalorimetric analysis which is different from the required limitation.

### **Claim Rejections - 35 USC § 102**

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

2. Claims 1, 6-8, and 26-30 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Aghajari et al. (March 1998).

3. Aghajari et al. describes a method identifying a compound that is an allosteric modulator an alpha-amylase wherein the chloride binding site is situated ~5 Å from the active site (distal site) (Abstract etc. and page 564, column 2, lines 8-10). Alpha-amylases catalyze the hydrolysis of starch etc. (page 564, column 1, lines 1-7), as in instant claims 1 and 26-30, a).

4. The chloride binding site has the dimensions and chemical properties specified in Table 1 (page 568, column 1, The chloride binding site and allosteric activation section), as in instant claim 1 and 26-30, b).

5. The triangular and nearly planar organization of the chloride ligands is also striking structural feature of the anion binding site (page 568, column 1, The chloride binding site and allosteric activation section), as in instant claim 1 and 26-30, c).

6. By site directed mutagenesis, the unidentate coordination of chloride by Lys 300 has been determined to account for the 20-fold lower binding constant reported for AHA with respect to the Arg-mediated binding of chloride in PPA. Chloride binding induces a dramatic increase of the catalytic constant  $k_{cat}$  as well as a shift of the optimum pH of activity from pH ~5 to neutrality (page 568, column 1, The chloride binding site and allosteric activation section). Aghajari et al. cites references to provide support for the above-cited in vitro data. The citation above has been reasonably construed as determined from in vitro type of assays, as in instant claim 1 and 26-30, d).

7. The triangular and nearly planar organization of the chloride ligands is also striking structural feature of the anion binding site. Chloride is bound close to Glu 233. The anion is situated 5.4Å from Glu 200 CD and can neutralize its partial positive charge induced by the carbonyl part of the carboxylic group (page 568, column 1, The chloride binding site and allosteric activation section), as in instant claim 6.

8. The method of Aghajari et al. comprises the detection of inhibition of alpha-amylase by Tris (page 568, column 1, Inhibition by Tris section), as in instant claim 7.

Art Unit: 1631

9. Chloride binding induces a dramatic increase of the catalytic constant  $k_{cat}$  as well as a shift of the optimum pH of activity from pH ~5 to neutrality (page 568, column 1, The chloride binding site and allosteric activation section), as in instant claim 8.

## CONCLUSION

13. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

14. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

15. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Art Unit: 1631

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571)272-0718.

C. Dune Ly / *CDL*  
6/8/05

*Ardin H. Marschel 6/12/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**